

House File 2231 - Introduced

HOUSE FILE 2231

BY R. TAYLOR

A BILL FOR

1 An Act concerning the use of experimental treatments for
2 patients with a terminal illness.
3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

1 Section 1. NEW SECTION. 144E.1 Title.

2 This chapter shall be known and may be cited as the "*Right*
3 *to Try Act*".

4 Sec. 2. NEW SECTION. 144E.2 Definitions.

5 As used in this chapter:

6 1. "*Eligible patient*" means an individual who meets all of
7 the following conditions:

8 a. Has a terminal illness, attested to by the patient's
9 treating physician.

10 b. Has considered all other treatment options approved by
11 the United States food and drug administration.

12 c. Has received a recommendation from the individual's
13 physician for an investigational drug, biological product, or
14 device.

15 d. Has given written informed consent for the use of the
16 investigational drug, biological product, or device.

17 e. Has documentation from the individual's physician that
18 the individual meets the requirements of this subsection.

19 2. "*Investigational drug, biological product, or device*"
20 means a drug, biological product, or device that has
21 successfully completed phase 1 of a United States food and drug
22 administration-approved clinical trial but has not yet been
23 approved for general use by the United States food and drug
24 administration and remains under investigation in a United
25 States food and drug administration-approved clinical trial.

26 3. "*Terminal illness*" means a progressive disease or medical
27 or surgical condition that entails significant functional
28 impairment, that is not considered by a treating physician to
29 be reversible even with administration of treatments approved
30 by the United States food and drug administration, and that,
31 without life-sustaining procedures, will soon result in death.

32 4. "*Written informed consent*" means a written document that
33 is signed by the patient, a parent of a minor patient, or a
34 legal guardian or other legal representative of the patient and
35 attested to by the patient's treating physician and a witness

1 and that includes all of the following:

2 *a.* An explanation of the products and treatments approved by
3 the United States food and drug administration for the disease
4 or condition from which the patient suffers.

5 *b.* An attestation that the patient concurs with the
6 patient's treating physician in believing that all products
7 and treatments approved by the United States food and drug
8 administration are unlikely to prolong the patient's life.

9 *c.* Clear identification of the specific proposed
10 investigational drug, biological product, or device that the
11 patient is seeking to use.

12 *d.* A description of the best and worst potential outcomes
13 of using the investigational drug, biological product, or
14 device and a realistic description of the most likely outcome.
15 The description shall include the possibility that new,
16 unanticipated, different, or worse symptoms might result
17 and that death could be hastened by use of the proposed
18 investigational drug, biological product, or device. The
19 description shall be based on the treating physician's
20 knowledge of the proposed investigational drug, biological
21 product, or device in conjunction with an awareness of the
22 patient's condition.

23 *e.* A statement that the patient's health plan or third-party
24 administrator and provider are not obligated to pay for any
25 care or treatments consequent to the use of the investigational
26 drug, biological product, or device, unless they are
27 specifically required to do so by law or contract.

28 *f.* A statement that the patient's eligibility for hospice
29 care may be withdrawn if the patient begins curative treatment
30 with the investigational drug, biological product, or device
31 and that care may be reinstated if this treatment ends and the
32 patient meets hospice eligibility requirements.

33 *g.* A statement that the patient understands that the
34 patient is liable for all expenses consequent to the use of
35 the investigational drug, biological product, or device and

1 that this liability extends to the patient's estate unless
2 a contract between the patient and the manufacturer of the
3 investigational drug, biological product, or device states
4 otherwise.

5 Sec. 3. NEW SECTION. **144E.3 Manufacturer rights.**

6 1. A manufacturer of an investigational drug, biological
7 product, or device may make available and an eligible patient
8 may request the manufacturer's investigational drug, biological
9 product, or device under this chapter. This chapter does not
10 require a manufacturer of an investigational drug, biological
11 product, or device to provide or otherwise make available the
12 investigational drug, biological product, or device to an
13 eligible patient.

14 2. A manufacturer described in subsection 1 may do any of
15 the following:

16 a. Provide an investigational drug, biological product, or
17 device to an eligible patient without receiving compensation.

18 b. Require an eligible patient to pay the costs of, or the
19 costs associated with, the manufacture of the investigational
20 drug, biological product, or device.

21 Sec. 4. NEW SECTION. **144E.4 Treatment coverage.**

22 1. This chapter does not expand the coverage required of an
23 insurer under Title XIII, subtitle 1.

24 2. A health plan, third-party administrator, or
25 governmental agency may provide coverage for the cost of an
26 investigational drug, biological product, or device, or the
27 cost of services related to the use of an investigational drug,
28 biological product, or device under this chapter.

29 3. This chapter does not require any governmental agency
30 to pay costs associated with the use, care, or treatment of a
31 patient with an investigational drug, biological product, or
32 device.

33 4. This chapter does not require a hospital licensed under
34 chapter 135B or other health care facility to provide new or
35 additional services.

1 Sec. 5. NEW SECTION. **144E.5 Heirs not liable for treatment**
2 **debts.**

3 If a patient dies while being treated by an investigational
4 drug, biological product, or device, the patient's heirs are
5 not liable for any outstanding debt related to the treatment
6 or lack of insurance due to the treatment, unless otherwise
7 required by law.

8 Sec. 6. NEW SECTION. **144E.6 Provider recourse.**

9 1. The board of medicine created under chapter 147 shall
10 not revoke, fail to renew, suspend, or take any action
11 against a physician's license based solely on the physician's
12 recommendations to an eligible patient regarding access to or
13 treatment with an investigational drug, biological product, or
14 device.

15 2. To the extent consistent with federal law, an entity
16 responsible for Medicare certification shall not take action
17 against a physician's Medicare certification based solely on
18 the physician's recommendation that a patient have access to an
19 investigational drug, biological product, or device.

20 Sec. 7. NEW SECTION. **144E.7 State interference.**

21 An official, employee, or agent of this state shall not
22 block or attempt to block an eligible patient's access to
23 an investigational drug, biological product, or device.
24 Counseling, advice, or a recommendation consistent with medical
25 standards of care from a licensed physician is not a violation
26 of this section.

27 Sec. 8. NEW SECTION. **144E.8 Private cause of action.**

28 1. This chapter shall not create a private cause of
29 action against a manufacturer of an investigational drug,
30 biological product, or device or against any other person
31 or entity involved in the care of an eligible patient using
32 the investigational drug, biological product, or device
33 for any harm done to the eligible patient resulting from
34 the investigational drug, biological product, or device, if
35 the manufacturer or other person or entity is complying in

1 good faith with the terms of this chapter and has exercised
2 reasonable care.

3 2. This chapter shall not affect any mandatory health care
4 coverage for participation in clinical trials under Title XIII,
5 subtitle 1.

6 EXPLANATION

7 The inclusion of this explanation does not constitute agreement with
8 the explanation's substance by the members of the general assembly.

9 This bill, titled the "Right to Try Act", permits
10 manufacturers of investigational drugs, biological products, or
11 devices to make available, and eligible patients with terminal
12 illnesses to attempt treatment with, an investigational
13 drug, biological product, or device as long as they provided
14 written informed consent. The bill defines the terms "eligible
15 patient", "terminal illness", "investigational drug, biological
16 product, or device", and "written informed consent".

17 Under the bill, an eligible patient's physician must
18 acknowledge that the patient's illness is terminal and
19 recommend the patient try an investigational drug, biological
20 product, or device. The patient's written informed consent
21 must acknowledge that treatments currently approved by the
22 United States Food and Drug Administration are unlikely to
23 prolong the patient's life. It must identify the specific
24 treatment sought and the potential best, worst, and expected
25 results from the treatment. It must acknowledge that the
26 patient's insurance is not required to pay for the treatment
27 and that any hospice service may refuse to accept the patient
28 after receiving the treatment. It must also acknowledge
29 that expenses will be credited to the patient, including the
30 patient's estate, unless an agreement with the manufacturer of
31 an investigational drug, biological product, or device states
32 otherwise. If the patient dies during treatment, the patient's
33 heirs are not liable for any remaining debts unless otherwise
34 required by law.

35 The manufacturer of an investigational drug, biological

1 product, or device may charge an eligible patient or provide
2 the treatment free of charge. Governmental entities are
3 not required to pay costs associated with the use, care, or
4 treatment of a patient with an investigational drug, biological
5 product, or device. The bill does not require hospitals
6 licensed under chapter 135B or other health care facilities to
7 provide new or additional services.

8 The board of medicine shall not take an adverse action
9 against a physician's license solely for recommending an
10 investigational drug, biological product, or device for the
11 physician's eligible patient. The bill does not create a new
12 private cause of action against any person or entity involved
13 in the care of an eligible patient using the investigational
14 drug, biological product, or device for any harm done to the
15 patient resulting from the treatment if the person or entity
16 is complying in good faith with the terms of the bill and has
17 exercised reasonable care.